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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,311	06/22/2001	Jeffry G. Weers	0103.00	9537

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EXAMINER	
STILLER, KARL J	

ART UNIT	PAPER NUMBER
1617	2

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/888,311	Applicant(s) WEERS ET AL.	
	Examiner Karl Stiller	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claims 2-4, 11-13, and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Regarding Claims 2-3, it is unclear as to how the recited emitted dose percentages therein further limits the base claim. The emitted dose of the dry powder is an inherent property of the method employing the dry powder and passive dry powder inhaler recited in the base claim. Regarding Claim 4, it is unclear as to how the recited FPF_{4+F} further limits the base claim. The recited FPF_{4+F} is seen to be an inherent property of the method recited in the base claim and therefore does not represent an active method step further limiting the method recited in the base claim. Regarding Claims 11-13, the recitation of an inherent property of the method employing the inhaler and drug powder of the base claim, i.e., lung deposition, does not further limit the method of the base claim. Regarding Claim 19, the recitation of an inherent property of the method employing the inhaler and drug powder of the base claim, i.e., Tmax, does not further limit the method of the base claim.

Claim 4 is objected to because it includes the abbreviation "FPF_{4+F}" rather than "fraction of fine particles depositing on stage 4 and the filter in the multi-stage liquid impinger, independent of flow rate". Because an abbreviation can be representative of a number of different entities, applicant should amend the claim to recite the proper

name of the claimed limitation. For example, the similar abbreviation "$FPF_{3.3\mu m}$" (see specification, p. 6, lines 23-25) means the fraction of particles emitted from the passive DPI device with a mass median aerodynamic diameter of 3.3μm and below is substantially different. Appropriate correction is required.

Claims 8-10 are objected to because of the following minor informalities: It is unclear as to what object the flow rate refers to. The insertion of "of the inhaler" after "flow rate" would be favorably considered in this regard.

Claim 14 is objected to because it includes the abbreviation "PTH" rather than "parathyroid hormone". Because an abbreviation can be representative of a number of different entities, applicant should amend the claim to recite the proper name of the active claimed in the method of administration. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in Claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as

to what degree device resistance may influence the emitted dose and to what degree flow rate may influence lung deposition and still be considered "substantially" independent.

The phrase "resulting in an emitted dose substantially independent of device resistance and lung deposition substantially independent of inhalation flow rate" is a phrase which renders the claim indefinite. The claim is indefinite as to what method steps are required to achieve this result.

The phrase "FPF_{4+F} of at least 60%" in Claim 4 is a relative phrase which renders the claim indefinite. The phrase " FPF_{4+F} of at least 60%" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear as to what FPF_{4+F} is 60% of.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. (WO 97/40819) and Van Oort et al. (WO 97/36574) in view of Edwards et al. (WO 98/31346).

Schultz et al. discloses a method of administering a dry powder drug composition comprising the steps of 1) providing a dry powder drug composition having a drug particle size of from about 1-7 microns and a mass median aerodynamic diameter of from about 3 to 7 microns, 2) loading the composition into an inhaler which is generally flow rate independent, and with the inhaler having an inspiration flow resistance of about 0.12 to 0.21 $(cmH_2O)^{1/2}$ over the range of about 15-60 L/min, and 3) inhaling the drug composition at an inspiration flow rate of about 15-60 L/min (see abstract, lines 1-5, p. 6, lines 1-23, p. 7, Claim 1 through p. 8, Claim 11).

Van Oort et al. discloses a method of administering a dry powder drug composition which may comprise an anti-inflammatory drug such as budesonide or an anti-infective drug which would include amphotericin B, comprising the steps of 1) providing a dry powder drug composition having a hollow particle size of from about 1 to 5 microns in size and a mass median aerodynamic diameter from about 0.5 to 7 microns, and 2) inhaling at a rate of 60 L/min (see p. 10, lines 9-12, p. 17, Table B, p. 18, lines 16-21).

The references do not particularly disclose a solid or hollow particulate dry powder with a bulk density of less than $0.5g/cm^3$ and a particle size of 1 to 30 microns comprising a lipid matrix recited herein, or an emitted dose of at least 60%, or a FPF_{4+F} of at least 60%, or lung deposition greater than 25%, or achieving a Tmax within 15 minutes of inhalation.

Edwards et al. discloses phospholipid matrix containing particles with a mass mean diameter between 5 and 30 microns and a tap (bulk) density of $0.4g/cm^3$ which

together yield an aerodynamic diameter of the particles of between 1 and 5 microns for use in a method of administration employing a passive dry powder inhaler (see abstract, lines 3-9, p. 6, lines 2-13, p. 8, lines 11-21, p. 9, lines 12-13, p. 11, lines 23-27, p. 33, lines 23-29).

It would have been obvious at the time the invention was made to modify the methods disclosed by Schultz et al. and Van Oort et al. by employing a solid or hollow particulate dry powder with a bulk density of less than $0.5g/cm^3$ and a particle size of 1 to 30 microns comprising a lipid matrix recited herein since Edwards et al. discloses phospholipid matrix containing particles of a size within the recited range which meet the density and aerodynamic diameter limitations of the instant invention which are useful in the same method of administration. It would also have been obvious to modify the methods of administration disclosed to achieve an emitted dose of at least 60%, or a FPF_{4+F} of at least 60%, or lung deposition greater than 25%, or achieving a Tmax within 15 minutes of inhalation of the dry powder drug composition herein by adjusting the particulate size and/or density since the optimization of a dosage regimen for active agents or amounts of an active to be administered is considered within the skill of the artisan as optimization of a result effective parameter. See *In re Boesch* 205 USPQ 215.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Minna Moezie

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Stiller: ks
November 29, 2001